Macro Specializing in Adverse Events Reporting
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ABSTRACT
One of the difficult tasks when displaying Adverse Event summaries using the SAS procedure, PROC REPORT, is to organize and display the information in a readable format. The macro was written with the expectation that a "BREAK after variable represented by &fst2ndlv / skip" is used in PROC REPORT. To begin, the macro call itself is straightforward and is described below:

%macro ae_sum (in_dsn = , brk_var = , fst2ndlv = , num_line = , minsubro = ) ;

where the macro parameter, &in_dsn is the name of the data set ready for PROC REPORT, containing a formatted text field concatenating, typically having the n's and %'s of subjects for adverse events by SOC and preferred term for each of the treatments (represented by different variables); &brk_var is the name of the non-display variable which provides the first level term, typically the SOC term to be grouped in the DEFINE statement in PROC REPORT and will provide the basis for the skip function on the BREAK statement; &fst2ndlv is the name of the variable that contains values of first and second level terms across observations; and &num_line is the number of lines available for data for each page of output (after considering titles, headers and footnotes) &minsubro is the minimum number of rows that can exist under the first level term at the bottom of a page when the first level term spans more than one page.

ASSUMPTIONS
There are some assumptions before the programming flow of the macro is described. The first assumption requires that the adverse events for a particular summary table have already been summarized and are ready to be used in a PROC REPORT procedure which would not summarize using a compute function. A data set is already available with variables representing columns (typically including SOC/Preferred terms and treatments) which are well formatted to appear in the report (typically including aligned counts and percentages contained within parentheses). The sort order has already been established. A single variable contains the first and second levels (SOC and preferred term) which are generally presented in the first column. Another variable exists which always contains the first level term (SOC term) always appear above the lower level terms represented. The first level term is displayed on the first page it appears or retained and labeled as "continuing" from the previous page. As a result of both client demands and statistician requests, a macro has been developed to add the current SOC term from the previous page and its contents with the text, "(cont.)" concatenated to the end of the text portion of the SOC term. This feature provides the reader of the adverse event summary continuity of the SOC term in that he/she will know exactly which preferred terms refer to a particular SOC term without having to turn back a page to see which SOC term goes with the preferred terms. This paper describes the programming flow of the macro to generate the desired output. The SAS macro will be called %KP1STLVL.SAS.

INTRODUCTION
This paper is intended to describe the programming logic flow in the macro that is used to generate the desired output. More specifically, the paper will describe the functions of the macro variables that are passed through the invocation of the macro in an easy-to-understand narrative. The scope of the paper is intended for presenting Adverse Event summaries using either a PROC REPORT or a DATA _NULL_. With respect to PROC REPORT, a FLOW option may not be used with the SOC term, since it is assumed that the number of lines needed will be sufficient for reporting purposes.

DISCUSSION
To begin, the macro call itself is straightforward and is described below:

The resulting data set after completion of the macro is ready for PROC REPORT or data _null_. To use the functionality of the macro, the PROC REPORT statement needs to have the variable _cntpg added to the COLUMN definition, needs to have _cntpg as a non-display variable in the DEFINE statements, and needs to have the following statement: "BREAK after _cntpg / page;". The macro was also written with the expectation that a "BREAK after variable represented by &fst2ndlv / skip" is used in PROC REPORT.

PROCESS
The process of the macro is described below:

The first step of the macro is to create a variable within the &in_dsn data set which documents the inbound order of the data set.

The second step is to retain data from the first level term observation - in case its needed for subsequent pages.

The third step of the macro is to establish points where the page will break, considering additional records will be added when the same first level term is reported on multiple pages. Also considered is the minimum number of terms that can appear below a first level term at the bottom of the page before the macro can span multiple pages. For example, the first level term cannot appear at the bottom of the page if none or one preferred terms appear, followed by the next page with remaining terms. The variable _cntpg increments for each successive page.

The last step is to add another observation which repeats the first level term observation, concatenating a "(cont.)" to the end of the term, when the first level term spans multiple pages.

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The inbound data set is changed in three ways. The inbound sorting is documented with the newly created variable _inorder. Additional observations are created to present the first level terms on subsequent pages. And the variable _cntpg is created which establishes page breakpoints for PROC REPORT.

The functionality of the macro minimizes “white space” on the page, re-prints desired first level term information, and clearly identifies when first level terms span multiple pages. Its functionality is not dependent on the decisions made regarding treatment headers, and is useful regardless if the columns represent treatments, subgroups, or TEAE/nonTEAE classifications. The functionality is not dependent on any particular sort order of the data, and is useful if the report needs to be sorted alphabetically or by decreasing frequency. Provided the assumptions described earlier are met, the macro can be inserted easily into already existing code when this functionality is desired or requested.

**CONCLUSION**

This macro currently provides a method to carry forward body systems to subsequent pages allowing the reviewer to have a point of reference regarding counts of preferred terms within a body system. Currently, the macro assumes that all rows on report are represented by rows in the data set. Efforts to improve the macro are planned which will allow PROC REPORT use of the flow option for the column containing the Body system/preferred term.

**CONTACT INFORMATION**

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